DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 24, 2015

Synergetics™
Mr. Mark Job
Reviewer
Regulatory Technology Services
1394 25th Street NW
Buffalo, MN 55313

Re: K143123
Trade/Device Name: PHOTON EX™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: MPA
Dated: February 5, 2015
Received: February 9, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Post market Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, MD
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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PHOTON EX - 510(k) Submission

Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Synergetics PHOTON EX

Indications for Use: The intended use of the device is to illuminate the eye during anterior and posterior vitreoretinal surgery.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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PHOTON EX - 510(k) Submission

Section 5 - 510(k) Summary

Submitted in accordance with the requirements of 21 CFR 807.92

I. SUBMITTER

Applicant's Name and Address:	Synergetics 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Dan Regan, Regulatory Affairs Director
Date Prepared:	September 16, 2014

II. DEVICE

Device Trade Name:	PHOTON EX
Common Name:	Ophthalmic Light Source
Device Classification:	Class II
Class Name:	Endoscope and Accessories (21 CFR 876.1500)
Product Code:	MPA
FDA Panel:	Ophthalmic

III. PREDICATE DEVICE

Predicate Device:	Synergetics Synerlight FiberOptic Lightsource, K032598

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IV. DEVICE DESCRIPTION

The PHOTON EX is a table-top, xenon lamp lightsource used for intraocular illumination during vitreoretinal surgery. The lightsource employs two channels from a single lamp. The channels terminate with entry ports on the unit's front panel. Each channel has a dedicated filter wheel; the filter wheels include the following band pass filters with an upper cut-off at 650 nm and lower cut-offs at 435nm, 455nm, 475nm, and 515nm respectively. The user inputs are controlled by membrane switches on the front panel.

V. INDICATIONS FOR USE

The intended use of the device is to illuminate the eye during anterior and posterior vitreoretinal surgery.

VI. COMPARISION OF TEHCNOLOGICAL CHARACTERISITICS WITH THE PREDICATE DEVICE:

	Subject Device	**Predicate Device**
Element	**PHOTON EX**	**Synerlight (PHOTON)**
510(k) Number	To be assigned	K032598
Product Code	MPA	MPA, GEX
Lamp	75 Watt Xenon	75 Watt Xenon
Consumable Connectors	Generic Multiport Tubing Cut-off	Generic Multiport Tubing Cut-off
Multiport Connector Location	Internal, Front Panel	External, Front & Side Panel

PHOTON EX - 510(k) Submission

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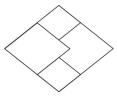
VI. COMPARISION OF TEHCNOLOGICAL CHARACTERISITICS WITH THE PREDICATE DEVICE:

	Subject Device	**Predicate Device**
Element	**PHOTON EX**	**Synerlight (PHOTON)**
Method of Control	Digital	Analog
User Interface	Membrane Switches on front panel	Analog dial adjacent to multiport connection
Filter Selection	Selectable filter wheel with 650nm upper cut off and lower cut offs of 435nm, 455nm, 475nm, and 515nm	Fixed filter wheel with 650nm upper cut off and a lower cut-off of 435nm
Unit Height x Width x Depth	8.1” x 13.2” X 12.6”	9” x 9.5”x 6.8”
Unit weight	18.5 pounds	13.28 pounds
Electrical power specifications	100-120V 220-240V 50/60 Hz	100-120V 220-240V 50/60 Hz
Consumables provided sterile (sold independent of device)	Yes	Yes
Consumables method of sterilization	ETO	ETO
Consumables Sterility Assurance Level	10^{-6}	10^{-6}



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VII. Summary of Non-clinical tests:

The PHOTON EX has undergone testing and complies with the applicable requirements of safety standards. The subject device performed equivalently to the predicate device in a comparative bench test. Therefore, the subject device and the predicate device have similar safety, effectiveness, and performance profiles.

VIII. Substantial Equivalence Basis:

The conclusions performed by independent laboratories and internal comparative bench testing provide objective evidence to substantiate the Synergetics PHOTON EX is as safe and effective as the predicate device, the Synergetics Synerlight.